Current open procedures for treatment of tumors are extremely disruptive and cause a great deal of damage to healthy tissue. During the surgical procedure, the physician must exercise care in not cutting the tumor in a manner that creates seeding of the tumor, resulting in metastasis. In recent years, development of products has been directed with an emphasis on minimizing the traumatic nature of traditional surgical procedures.

D2

On page 5, please replace the paragraph starting on line 6 with the following:

There is a need for an RF treatment device which provides for multi-modality treatment of selected tissue sites which includes a catheter with a single entrance tract for an RF treatment electrode, an introducer, an insulator sleeve and a fluid infusion device. It would be desirable to provide an RF treatment apparatus which maintains a selected power at the electrode independent of changes in voltage or current.

D3

On page 8, please replace the paragraph starting on line 20 with the following:

Hardware and software, collectively "resources," maintain a selected power at the electrode and include a power supply, power circuits, controller, user interface and display, a device to calculate power and impedance, current and voltage sensors and a temperature measurement device. The controller can be under microprocessor control. Imaging of the tumor, through ultrasound, CT scanning, and the like, can be utilized to first define the boundaries of the tumor mass. Images of the tumor are then imported to a display. Individual electrode needles are thereafter positioned in or surround the tumor, and RF energy is then slowly delivered to the tumor. Prior treatment planning of the tumor assists in the effective delivery of RF treatment energy. Through imaging, tissue characterization by monitoring the process, is achieved. The electrodes are used in the bipolar mode.

D4

On page 12, please delete the paragraphs on lines 1 through 23.

On page 12, please replace the paragraph starting on line 25 with the following:

Figure 10 is a block diagram of an embodiment of the invention which includes a microprocessor.

D5

On page 12, please replace the paragraph starting on line 28 with the following:

Figure 11 illustrates the use of two RF treatment apparatus, such as the one illustrated in Figure 1(a), that are used in a bipolar mode.

D6

On page 12 please replace the paragraphs starting on line 29 (added by the amendment mailed January 18, 2002) with the following:

FIG. 12 is a planar view of a stylet ablation device of this invention.

FIG. 13 is fragmentary cross-sectional view of the tip of the stylet of FIG. 1 with the electrode extended from the tip.

D7

FIG. 14 is a schematic view showing use of an embodiment with a shape memory electrode preformed into a curved shape to ablate a tissue mass.

On page 13, please replace the paragraph starting on line 4 with the following:

Referring now to Figures 1(a), 1b), 1(c), 2 and 3, an RF treatment apparatus 10 is illustrated which can be used to ablate a selected tissue mass, including but not limited to a tumor, or treat the mass by hyperthermia. Treatment apparatus 10 includes a catheter 12 with a catheter lumen in which different devices are introduced and removed. An insert 14 is removably positioned in the catheter lumen. Insert 14 can be an introducer, a needle electrode, and the like.

D8

On page 14, please replace the paragraph starting on line 1 with the following:

Electrode 16 is then advanced out of a distal end of insert 14, and the length of an electrode conductive surface is defined, as explained further in this specification. Electrode 16 can advance straight, laterally or in a curved manner out of distal end of insert 14. Ablative or hyperthermia treatment begins when two electrodes 16 are positioned closely enough to effect bipolar treatment of the desired tissue site or tumor. A return electrode attaches to the patient's skin. Operating in a bipolar mode, selective ablation of the tumor is achieved. However, it will be appreciated that the present

D9

invention is suitable for treating, through hyperthermia or ablation, different sizes of tumors or masses. The delivery of RF energy is controlled and the power at each electrode is maintained, independent of changes in voltage or current. Energy is delivered slowly at low power. This minimizes desiccation of the tissue adjacent to the electrodes 16, permitting a wider area of even ablation. In one embodiment, 8 to 14 W of RF energy is applied in a bipolar mode for 10 to 25 minutes, An ablation area between electrodes 16 of about 2 to 6 cm is achieved.

On page 14, please replace the paragraph starting on line 29 with the following:

Also included is an insulator sleeve 20 coupled to an insulator slide 22. Insulator sleeve 20 is positioned in a surrounding relationship to electrode 16. Insulator slide 22 imparts a slidable movement of the insulator sleeve along a longitudinal axis of electrode 16 in order to define an electrode conductive surface that begins at an insulator sleeve distal end.

On page 15, please replace the paragraph starting on line 5 with the following:

A thermal sensor 24 can be positioned in or on electrode 16 or introducer 18. A thermal sensor 26 is positioned on insulator sleeve 20. In one embodiment, thermal sensor 24 is located at the distal end of introducer 18, and thermal sensor 26 is located at the distal end of insulator sleeve 20 at an interior wall which defines a lumen of insulator sleeve 20. Suitable thermal sensors include a T type thermocouple with copper constantene, J type, E type, K type, thermistors, fiber optics, resistive wires, thermocouples IR detectors, and the like. It will be appreciated that sensors 24 and 26 need not be thermal sensors.

On page 15, please replace the paragraph starting on line 14 with the following:

Catheter 12, insert 14, electrode 16 and introducer 18 can be made of a variety of materials. In one embodiment, catheter 12 is black anodized aluminum, 0.5 inch, electrode 16 is made of stainless steel, preferably 18 gauge, introducer 18 is made of stainless steel, preferably 21 gauge, and insulator sleeve 20 is made of polyimide.

On page 16, please replace the paragraph starting on line 14 with the following:

In another embodiment of RF treatment apparatus 10, electrode 16 is directly attached to catheter 12 without insert 14. Introducer 18 is slidably positioned in the lumen of electrode 16. Insulator sleeve 20 is again positioned in a surrounding relationship to electrode 16 and is slidably moveable along its surface in order to define the conductive surface. Thermal sensors 24 and 26 are positioned at he distal ends of introducer 18 and insulator sleeve 20. Alternatively, thermal sensor 24 can be positioned on electrode 16, such as at its distal end. The distal ends of electrode 16 and introducer 18 can be sharpened and tapered. This assists in the introduction of RF treatment apparatus to the desired tissue site. Each of the two distal ends can have geometries that essentially match. Additionally, distal end of introducer 18 can be an essentially solid end in order to prevent the introduction of material into the lumen of catheter 16.

D13

On page 17, please replace the paragraph starting on line 27 with the following:

Referring now to Figures 4(a) and 4(b), infusion device 50 is attached to the distal end of catheter 12 and retained by a collar. The collar is rotated, causing catheter 12 to become disengaged from infusion device 50. Electrode 16 is attached to the distal end of catheter 12. Catheter 12 is pulled away from infusion device 50, which also removes electrode 16 from infusion device 50. Thereafter, only infusion device 50 is retained in the body. While it remains placed, chemotherapeutic agents can be introduced through infusion device 50 to treat the tumor site. Additionally, by leaving infusion device 50 in place, catheter 12 with electrode 16 can be reintroduced back into the lumen of infusion device 50 at a later time for additional RF treatment in the form of ablation or hyperthermia.

D14

On page 19, please replace the paragraph starting on line 10 with the following:

Once chemotherapy is completed, electrode 16 and catheter 12 can be introduced through infusion device 50. RF power is then delivered to the tumor site. The process begins again with the subsequent removal of catheter 12 and electrode 16 from infusion

D15

device 50. Chemotherapy can then begin again. Once it is complete, further RF power can be delivered to the tumor site. This process can be repeated any number of times for an effective multi-modality treatment of the tumor site.

On page 19, please delete the paragraph starting on line 23.

On page 19, please replace the paragraph starting on line 12 with the following:

In a similar manner, temperatures detected at thermal sensors 24 and 26 provide feedback for maintaining a selected power. The actual temperatures are measured at temperature measurement device 66, ad the temperatures are displayed at user interface 68. A control signal is generated by controller 59 that is proportional to the difference between an actual measured temperature, and a desired temperature. The control signal is used by power circuits 57 to adjust the power output in an appropriate amount in order to maintain the desired temperature delivered at he respective sensor 24 or 26.

On page 21, please replace the paragraph starting on line 20 with the following:

Controller 58 can be microprocessor controlled. Referring now to Figure 10, current sensor 62 and voltage sensor 64 are connected to the input of an analog amplifier 70. Analog amplifier 70 can be a conventional differential amplifier circuit for use with thermal sensors 24 and 26. The output of analog amplifier 70 is sequentially connected by an analog multiplexer 72 to the input of analog-to-digital converter 74. The output of analog amplifier 70 is a voltage which represents the respective sensed temperatures. Digitized amplifier output voltages are supplied by analog-to-digital converter 74 to a microprocessor 76. Microprocessor 76 may be a type 68HCII available from Motorola. However, it will be appreciated that any suitable microprocessor or general purpose digital or analog computer can be used to calculate impedance or temperature.

On page 23, please replace the paragraph starting on line 7 with the following:

The following examples illustrate the use of the invention with two RF treatment apparatus with two electrodes as shown in Figure 11, or a pair of two electrodes, that are used in a bipolar mode to ablate tissue.

On page 28 please replace the paragraphs starting on line 10 (added by the amendment mailed January 18, 2002) with the following:

Referring to the drawings, FIG. 12 is a planar view of a stylet ablation device of this invention. The device comprises a handle portion 112 and a delivery tube portion 114. Stylet sleeve control manual tab 116 and stylet electrode control manual tab 118 are mounted for sliding engagement in slots and in the handle top plate. Index markings 121 indicate the relative angle of orientation of the stylet with respect to the stylet angle indicator 123.

FIG. 13 is a cross-sectional view of the tip of the stylet ablation device, such as that shown in FIG. 12, with the electrode and sleeve extended. This embodiment shows a flexible stylet 150 having a predetermined curved configuration. The flexible stylet can also be straight, if the remote position can be reached by a straight path from the point of entry without damaging a vital body component. The electrode can be made of a shape memory alloy, shaped to revert to a desired configuration when released from the tubing. The configuration can be simple curves, a combination of straight portions and curves, curves with differing radii, in two or three dimensions, selected to direct the electrode and its surrounding flexible, highly conformable sleeve in a preselected two or three dimensional path through tissue to a site to be ablated.

A method of this invention for medical ablation of difficult to access tissues comprises inserting a hollow needle through a tissue layer. The needle encloses a conductive electrode of highly flexible memory metal having a predetermined curved memory configuration and a sharpened distal terminus. The electrode tube is enclosed within an insulating sleeve axially moveable thereon and bendable therewith. The electrode and sleeve are advanced from the terminal end of the hollow needle, whereby the portion of the electrode and sleeve advanced beyond the end of the needle adopt the

predetermined curved memory configuration and the electrode and sleeve follow a correspondingly predetermined curved path through tissue to the site to be ablated. Then a portion of the sleeve is withdrawn from the terminus of the electrode to expose a predetermined electrode area for ablation. Finally, RF energy is applied to the tissue surround the exposed electrode area to effect ablation thereof.

Referring to FIG. 14, use of an embodiment with a shape memory electrode preformed into a curved shape to ablate a near zero access area behind an obstruction in the body. The objective of the treatment is to reduce the size of a mass 154 behind a rigid obstacle, such as bone 156 (or area to be protected from penetration). The electrical conductor and sleeve is extended from the needle 140 through surrounding tissue around the obstacle to its back surface, and the target tissue to be reduced. The sleeve 136 is then withdrawn to a position exposing the electrode area required to ablate the tissue mass. Heat is generated in the target tissue from an electric current or electromagnetic field produced by the electrical conductor. Preferably, the volume of tissue being treated is controlled by moving the non-conductive sleeve to expose a selected length of electrode in the body tissue to be treated, the remaining area of the electrode remaining shielded by the sleeve to protect the intervening tissues. The amount and duration of the energy delivery is also varied to control the volume of tissue being treated. The current passes to a large surface area grounding plate contacting the outer skin surface.

D19 cont.

In the Drawings:

Please delete Figs. 10(a), 10(b), 10(c), 10(d), 10(e), 10(f), 10(g), and 10(h).

Applicants respectfully propose an amendment to Figure 1A as shown in the enclosed red-lined drawing page to add the lead line for reference character 30.

Applicants respectfully propose an amendment to Figures 1C and 1D as shown in the enclosed red-lined drawing page to add the reference characters.

Entry of the proposed amendment to the drawings in respectfully requested and a revised formal drawing page is submitted herewith.